UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,590	03/24/2004	Mark Girard	706195-2001	3798
Bingham McCutchen LLP 2020 K Street, NW Washington, DC 20006			EXAMINER	
			DESANTO, MATTHEW F	
Washington, DC 20006			ART UNIT	PAPER NUMBER
			3763	
			MAIL DATE	DELIVERY MODE
			08/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARK GIRARD, BENJAMIN BELL, and TODD BEAUPRE

Appeal 2009-009212 Application 10/807,590 Technology Center 3700

Before: LINDA E. HORNER, WILLIAM F. PATE III, and KEN B. BARRETT, *Administrative Patent Judges*.

HORNER, Administrative Patent Judge.

DECISION ON APPEAL<sup>1</sup>

\_

<sup>&</sup>lt;sup>1</sup> The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

# STATEMENT OF THE CASE

Mark Girard et al. (Appellants) seek our review under 35 U.S.C. § 134 of the Examiner's decision rejecting claims 1-10, 13-16, and 18-28, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM-IN-PART.

# THE INVENTION

Appellants' claimed invention is a port for subcutaneous implantation comprising a housing with two wells, each in fluid communication with one of two lumens of a substantially F-shaped flow element. Spec. 2, para. [0004]. Claim 1, reproduced below, is representative of the subject matter on appeal.

1. A port for subcutaneous implantation, comprising:

a housing including first and second wells formed therein; and

a substantially F-shaped flow element including first and second lumens extending therethrough wherein, when in an operative configuration the F-shaped flow element is coupled to the housing with a proximal end of each of the lumens in fluid communication with a respective one of the first and second wells for receiving fluid therefrom, and wherein distal ends of each of the lumens form outlets, each outlet being coupleable to a lumen of a medical catheter, the F-shaped flow element including first and second arms extending from a trunk with the first lumen extending through the first arm to the trunk and the second lumen extending through the second arm to the trunk, the first and second lumens being separated from one another within the trunk, the first arm including a first portion extending from an intersection with the second arm substantially parallel to the trunk and a second portion extending substantially parallel to the second arm, wherein the first portion of the first arm is separated from the housing by a gap.

# THE REJECTIONS

Appellants seek review of the following decisions by the Examiner:

- 1. Rejection of claims 1-10, 13-16, and 18-28 under 35 U.S.C. § 103(a) as unpatentable over Cupp (US 4,892,518, issued January 9, 1990) and Ensminger (US 5,542,923, issued August 6, 1996).
- 2. Rejection of claims 1-10, 13-16, and 18-28 under 35 U.S.C.§ 103(a) as unpatentable over Ensminger.

## **ISSUES**

The issues presented by this appeal are:

- 1. Would the substantially F-shaped flow element called for in claim 1 have been obvious to one having ordinary skill in the art in view of Cupp and Ensminger?
  - 2. Does Cupp disclose a partition as called for in claim 2?
- 3. Does Cupp disclose a first and second arm with a cross section as called for in claim 8?
- 4. Has the Examiner presented a prima facie case of obviousness for claims 3-7, 9, 10, 14-16, 18, 20, 21, and 23-28 under as being unpatentable over Cupp and Ensminger?
- 5. Does Ensminger disclose "a first portion extending from an intersection with the second arm substantially parallel to the trunk" as recited in independent claims 1, 13, 19, and 22?

#### **ANALYSIS**

# Claim Construction

Claim 1 is directed to a port for subcutaneous implantation comprising a housing with two wells, each in fluid communication with one of the two lumens of a substantially F-shaped flow element. Claim 1 further defines

the F-shaped flow element as including "first and second arms extending from a trunk" with the first and second lumens extending through the first and second arms, respectively, "the first and second lumens being separated from one another within the trunk, the first arm including a first portion extending from an intersection with the second arm substantially parallel to the trunk and a second portion extending substantially parallel to the second arm."

Appellants' Specification's definition of the "substantial F-shape" of the flow element does not require that the flow element precisely mimic the letter F. Spec. 8, para. [0016]; figs. 2, 3. Rather, Appellant's Specification describes that "the F-shape of the flow element 102 refers more generally to a configuration where 2 arms project from a common trunk substantially parallel to one another at an angle (e.g., of between 15° to 75°) with respect to the longitudinal axis of the trunk." *Id*.

We construe "substantially parallel" in the context of Appellants' claim and in light of the Specification, as largely, but not wholly, parallel.<sup>2</sup> *See York Prods, Inc. v. Cent. Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1573 (Fed. Cir. 1996) (construing the term "substantially" as "largely but not wholly that which is specified").

In light of these findings, we interpret claim 1 to require that the flow element generally resemble an F-shape by having have two arms projecting from a common trunk so that: (1) the second portion of the first arm and the second arm each extend from the longitudinal axis of the trunk at an angle; (2) the first arm includes a first portion extending from the intersection with

<sup>&</sup>lt;sup>2</sup> This interpretation seems consistent with Appellants' assertion that "substantially parallel" means "not perfectly parallel." App. Br. 6.

Application 10/807,590

the second arm largely, but not wholly, parallel to the trunk, and (3) the second portion of the first arm extends largely, but not wholly, parallel to the second arm.

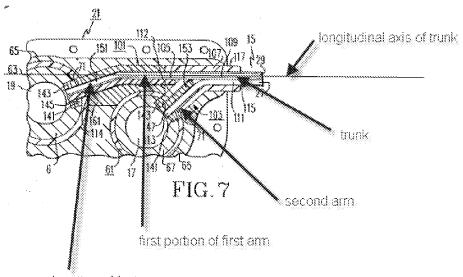
Rejection of claims 1-10, 13-16, and 18-28 under 35 U.S.C. § 103(a) as unpatentable over Cupp and Ensminger

Claims 1, 13, 19, and 22

Appellants argue independent claims 1, 13, 19, and 22 as a group. App. Br. 5-7; Reply Br. 2-4. We select claim 1 as the representative claim, and claims 13, 19, and 21 stand or fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellants assert two reasons why the proposed combination does not disclose the substantially F-shaped flow element called for in claim 1. First, Appellants contend that Cupp differs in that Cupp's Y-connector 107 is shaped like the letter Y, not like the letter F. App. Br. 5; Reply Br. 2-4.

An annotated version of Figure 7 of Cupp is reproduced below:



Cupp discloses a port assembly comprised of a port and a catheter assembly. Cupp, col. 1, 1l. 39-40. Figure 7 of Cupp depicts a fragmented view in longitudinal section of the catheter assembly 15. Cupp, col. 2, 1l. 60-62; fig. 7 (Arrows and labels added to identify portions relating to the flow element of claim 1). Cupp's port 13 includes inlet septum 17 and outlet septum 19. Cupp, col. 3, 1l. 43-44; fig. 1. The catheter assembly 15 is comprised of a long tubular member 101 and a short tubular member 103. Cupp, col. 4, 1l. 66-67; fig. 7.

With reference to Figure 7, Cupp uses the term "Y-connector 107" to refer to a connector used to join long tubular member 101 and short tubular member 103. Cupp, col. 4, ll. 66-67; col. 5, ll. 4-5; fig. 7. Correlating this disclosure to Appellants' claim language, Cupp is referring to the intersection of the second arm (short tubular member 103) and the trunk (the portion of long tubular member 101 at the Y-connector 107) as Y-shaped, while the claim refers the shape of the entire flow element as F-shaped. The analogous portion of Appellants' device (the junction of the second arm 130 to the trunk 132) is also Y-shaped. Spec. 8, para. [0016]; fig. 3. As such, the fact that Cupp describes its connector 107 between long tubular member 101 and short tubular member 103 as a "Y-connector" does not mean that Cupp's entire flow element cannot be F-shaped, as called for in claim 1.

Second, Appellants argue that the proposed combination does not disclose the claimed substantially F-shaped flow element because the arms of the proposed combination would not be substantially parallel. App. Br. 6.

As shown above in Figure 7, Cupp discloses that short tubular member 103 extends from inlet septum 17 to join long tubular member 101 at Y-connector 107 at an acute angle with respect to the longitudinal axis of

long tubular member 101. Cupp, col. 4, ll. 66-67; col. 5, ll. 4-5, 18-20; fig. 7. From the intersection with short tubular member 103, long tubular member 101 continues past inlet septum 17 for a first portion, then turns at an acute angle to its longitudinal axis for a second portion to enter outlet septum 19. Cupp, figs 2, 7. Cupp depicts the second portion of the first arm (the portion of long tubular member 101 entering outlet septum 19) and the second arm (short tubular member 103), as each extending at an acute angle from the longitudinal axis of the trunk (the portion of long tubular member 101 between Y-connector 107 to the end of the first portion where long tubular member 101 turns to join outlet septum 19). Cupp, fig. 7.

Thus, Cupp discloses a second portion of the first arm (the portion of long tubular member 101 entering outlet septum 19) that extends largely, but not wholly parallel to the second arm (short tubular member 103), so that the flow element as a whole substantially resembles the letter F as called for in claim 1.

Even were we to conclude that Cupp's second portion of the first arm (the portion of long tubular member 101 entering outlet septum 19) is not largely parallel to the second arm (short tubular member 103), this difference between Cupp's device and the claimed invention is not a meaningful one for purposes of an obviousness determination. At best, the only distinction between Cupp, as modified by Ensminger<sup>3</sup>, and Appellants' claimed invention is a slight deviation in angle of the second portion of the first arm from substantially parallel to the second arm.

\_

<sup>&</sup>lt;sup>3</sup> The Examiner relied on Ensminger to show a first arm separated from the housing by a gap. Ans. 3-4. Appellants do not contest this finding as to the scope and content of Ensminger, or the Examiner's stated reason for combining Cupp and Ensminger. *See* App. Br. 5-7.

Putting this minor distinction in context, nothing in Appellants' Specification describes that the substantially parallel relationship between the arms produces unexpected results, or is critical to operation of the device. Spec., *passim*. Appellants do not point to, nor do we see, an alteration in function of the flow element that would be caused if the relative position of the second portion of the first arm to the second arm deviates slightly from substantially parallel. App. Br. *passim*; Reply Br. *passim*. Such a small gap between the claimed invention and the prior art cannot be basis for a determination of nonobviousness over the prior art.

Rather, the minor distinction between the prior art and the claimed device appears to be an obvious variation of the prior art. *See KSR* at 417 (2007) (citing to *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976) (absent unexpected results, when a patent "simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such an arrangement, the combination is obvious.)).

Further, this case is analogous to the facts of *In re Dailey*, 357 F.2d 669, 672-73 (CCPA 1966). In *Dailey*, Appellant claimed a disposable nursing container for infants shaped as "a portion of a sphere less than a hemisphere." *Id.* at 670. The court held that Appellants had failed to establish the significance of the configuration of the container, so that the claimed shape was merely one of numerous shapes a person of ordinary skill in the art would find obvious. *Id.* at 672-673. Here, Appellants likewise have failed to establish the significance of the shape of the substantially F-shaped flow element, which appears to be but one of numerous shapes a person of ordinary skill in the art would find obvious.

As such, we will sustain the Examiner's rejection of independent claim 1 as being unpatentable over Cupp and Ensminger. Claims 13, 19, and 22 fall with claim 1.

Claims 2-10, 14-16, 18, 20, 21, and 23-28

In the office action that is the subject of this appeal, this rejection contains no findings related to dependent claims 2-10, 14-16, 18, 20, 21, and 23-28. Office Action dated November 1, 2007, pp. 2-4. Appellants note the lack of such findings. App. Br. 7. In response, the Examiner finds the partition of claim 2, and the cross section of the first and second arms of claim 8 are disclosed in Cupp's Figures 1 and 2. Ans. 8-9. Appellants do not contest either finding in the Reply Brief.

We agree with the Examiner that Cupp discloses the partition (partition 105) of claim 2 and the semi-circular cross section of the first and second arms of claim 8. Cupp, col. 5, ll. 7-11; figs. 1, 2, 7, and 9. As such, we sustain the rejection of claims 2 and 8. *Ex Parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential) (citing to *Hyatt v. Dudas*, 551 F.3d 1307, 1313-14 (Fed. Cir. 2008) for the proposition that the Board may treat arguments appellant failed to make as waived).

Regarding the remaining claims, the absence of adequate findings corresponding to each claim fails to put Appellants on notice of the reasons for the rejection. The Examiner has not made a prima facie case regarding claims 3-7, 9, 10, 14-16, 18, 20, 21, and 23-28. *Ex Parte Frye*, 94 USPQ2d at 1075 ("The Examiner has the initial burden to set forth the basis for any rejection so as to put the patent applicant on notice of the reasons why the

\_

<sup>&</sup>lt;sup>4</sup> The Examiner makes other general comments, but these comments do make adequate findings with respect to specific claims to address where the remaining claim limitations can be found in the references. *Id.* 

applicant is not entitled to a patent on the claim scope that he seeks – the so-called 'prima facie case.'" (citing *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992)). As such, we will sustain the Examiner's rejection of dependent claims 2 and 8, but are constrained to reverse the rejection of dependent claims 3-7, 9, 10, 14-16, 18, 20, 21, and 23-28.

Rejection of claims 1-10, 13-16, and 18-28 under 35 U.S.C. § 103(a) as unpatentable over Ensminger

Independent claims 1, 13, 19, and 22 each call for "a first portion [of a first arm] extending from an intersection with the second arm substantially parallel to the trunk."

Ensminger discloses an implantable infusion port that includes a pair of lumens 100 and 100' connected to outlet nipples 92 and 92' that converge to form multi-lumen catheter 90. Ensminger, col. 3, II. 9-10; col. 9, II. 58-65; fig. 4. Ensminger's first arm (lumen 100) joins the second arm (lumen 100') at the trunk (multi-lumen catheter 90), and does not include a first portion extending from the intersection with the second arm (lumen 100') substantially parallel to the trunk (multi-lumen catheter 90). *Id.* Because Ensminger does not disclose "a first portion extending from an intersection with the second arm substantially parallel to the trunk," we agree with Appellants (App. Br. 8; Reply Br. 4) that Ensminger does not disclose the substantially F-shaped flow element called for in independent claims 1, 13, 19, and 22. The rejection of claims 2-10, 14-16, 18, 20, 21, and 23-28 is also in error by virtue of their dependence from independent claims 1, 13, 19, and 22.

# **CONCLUSIONS**

The substantially F-shaped flow element called for in claim 1 would have been obvious in view of Cupp and Ensminger.

Cupp discloses a partition as called for in claim 2.

Cupp discloses a first and second arm with a cross section as called for in claim 8.

The Examiner failed to make a prima facie case with regard to claims 3-7, 9, 10, 14-16, 18, 20, 21, and 23-28 under 35 U.S.C. § 103(a) as unpatentable over Cupp and Ensminger.

Ensminger does not disclose "a first portion extending from an intersection with the second arm substantially parallel to the trunk" as recited in independent claims 1, 13, 19, and 22.

### **DECISION**

We AFFIRM the Examiner's decision to reject claims 1, 2, 8, 13, 19, and 22 under 35 U.S.C. § 103(a) as unpatentable over Cupp and Ensminger.

We REVERSE the Examiner's decision to reject claims 3-7, 9, 10, 14-16, 18, 20, 21, and 23-28 under 35 U.S.C. § 103(a) as unpatentable over Cupp and Ensminger.

We REVERSE the Examiner's decision to reject claims 1-10, 13-16, and 18-28 under 35 U.S.C. § 103(a) as unpatentable over Ensminger.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2007).

# **AFFIRMED-IN-PART**

Appeal 2009-009212 Application 10/807,590

nlk

BINGHAM McCUTCHEN, LLP 2020 K STREET NW WASHINGTON DC 20006